

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0124
CUSTOMER NO. 1828

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

SANOI AVENTIS
1041 ROUTE 202-206, MAILSTOP BRW JR2-203 A
BRIDGEWATER, NJ 08807
(908) 231-2334

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

(b)(2)High, (b)(7)f

1 Oct 2005 - 27 Feb 2006

NOV 21 2006

BY:

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	62	168	0	5	235
5. Cats	0	0	0	0	0
6. Guinea Pigs	138	278	2852	9	3722
7. Hamsters	0	0	0	0	0
8. Rabbits	0	13	0	0	13
9. Non-Human Primates	17	1	46	0	64
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

b6, b7c

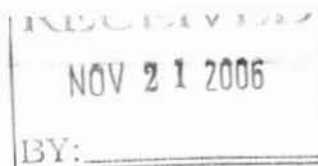
DATE SIGNED

11/17/06

APHIS FORM 7023 /
(AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete)

PART 1 - HEADQUARTERS



November 16, 2005

USDA Annual Report
Registration #: 22-R-0124 (1 Oct 2005 – 28 Feb 2006)

Explanation of Category 'E' Animals

1. Number of Animals and Species Used in:

b4

Used: 75 Dogs
Number of Category E animals: 3

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Used: 104 Dogs
Number of Category E animals: 2

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Used: 1780 Guinea pigs
Number of Category E animals: 9

2. Procedure Used:

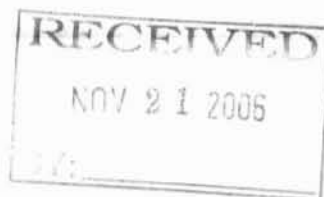
b4

3-dogs: 28-day oral toxicity study.

- 1 dog exhibited progressive clinical signs and was humanely euthanized.
- 2 dogs exhibited multiple episodes of emesis in conjunction with progressive clinical signs throughout the study.

b4

2-dogs: 3-month oral toxicity study. One dog had an intra-digital mass that could not be treated with analgesics because it was on study. One dog had decreased motor activity and other clinical signs throughout the study.



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9-guinea pigs – During a respiratory study animals developed severe responses and were euthanized or found dead.

3. Justification for procedure:

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– Toxicity Studies in Rats, Mice, Dogs, Rabbits, and Guinea Pigs

The international regulatory process to approve new drug formulations and candidate drugs requires drug safety assessments. The goal of these studies is to investigate the toxicity of a new drug or formulation. The administration of any pain relieving drugs to these animals could interact and alter the results of the study.

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– Guinea pig models for drug discovery

The guinea pig is a valuable animal model for the discovery and development of treatments and potential candidate drugs.

4. Procedure required by:

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Agency: FDA,
Federal Food, Drug, and Cosmetic Act CFR: 505 (4) (i) (1) (A)